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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,859	12/03/2001	Lee D. Arnold	BBC-059/A	9803

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EXAMINER	
AULAKH, CHARANJIT	
ART UNIT	**PAPER NUMBER**
1625	15

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/831,859	Arnold, L.D. et al.
Examiner	**Art Unit**
CHARANJIT AULAKH	1625

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 10, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) *14 and 26* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13, 15-25, and 27-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. According to paper no. 12 filed on June 10, 2002, the applicants have elected group I in response to restriction requirement. Claims 14 and 26 are withdrawn from further consideration as being drawn to non-elected inventions.

Response to Arguments

2. Applicant's arguments filed on June 10, 2002 (paper no. 12) regarding restriction requirement have been fully considered but they are not persuasive. The examiner does not agree with the applicants arguments that antibodies, peptides, ribozymes, antisense polynucleotides and the compounds all have the same common core and therefore, does not constitute a burdonsome search. Actually except the compound (which is elected by the applicants in response to restriction requirement), all other treatments such as antibodies, peptides, ribozymes and antisense polynucleotides are not examined in this art unit since they are classified in different classes and subclasses and therefore, constitutes a burdonsome search. The examiner agrees with the applicants arguments that all treatments have the same utility of treating hyperpermeability but this does not define the common core of all different treatments. However, the protection is being sought for different treatment regimens which are classified in different classes and subclasses and therefore, causes a burdonsome search. Thus, restriction requirement as indicated is proper and thereby made final.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 12 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating vascular hyperpermeability and therefore, edema, diapedesis and vascular hypotension, does not reasonably provide enablement for treating all other disorders such as brain tumors, liver cirrhosis etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:
Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight factors such

as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

The instant compound selectively inhibits KDR tyrosine kinase (see table on page 34) and more specifically catalytic responses of KDR/VEGFR-2 without affecting activity of Flt-1/VEGFR-1 and therefore, will have utility in treating vascular hyperpermeability and therefore, edema, diapedesis and vascular hypotension. However, there is no teaching in the specification or prior art that specific inhibitors of catalytic responses of KDR/VEGFR-2 without affecting activity of Flt-1/VEGFR-1 will treat all other disorders such as brain tumors, liver cirrhosis etc. There is no guidance or direction in the specification as well as no examples provided to show how the instant compound will have utility in treating all other disorders besides edema, diapedesis and vascular hypotension. In absence of such teachings and direction, it would require undue experimentation to demonstarte the effectiveness of the instant compound in treating disorders other than edema, diapedesis and vascular hypotension.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-13, 15-25 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-13 and 15 depend upon claim 1 and claims 17-25 and 27-29 depend upon claim 16. In claims 1 and 16, the terms " administering to said individual a compound and administartion of a

compound " are indefinite without specifying effective amount. The applicants are suggested to include the term " therapeutically effective amount of a " before compound.

Claims 11 and 18 are directed to using peptides and antibodies as compounds. However, peptides and antibodies are not compounds. An appropriate correction is required.

IMPROPER MARKUSH GROUP

8. Claims 1-13, 15-25 and 27-29 are objected as being directed to Improper Markush Group since antibodies, peptides, ribozymes, antisense polynucleotides and the compounds do not have the same common core. The applicants are suggested to amend the claims to read upon the elected group to overcome this objection specially in view of the fact that the restriction is made final.

Allowable Subject Matter

9. The following is a statement of reasons for the indication of allowable subject matter:

The instant method of inhibiting vascular hyperpermeability by administering the instant pyrazole compound (see compound on page 33) is allowable over the prior art since it is neither disclosed nor obvious over the prior art. In the prior art, Habeck (U.S. Patent no. 3,932,430) discloses substituted naphtho pyrazoles (see examples 4-6 and 10-12) as anti-fertility and antihypertensive agents. However, there is no teaching or suggestion for using these compounds for treating vascular hyperpermeabilty.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.

C. S. Aulakh

CHARANJIT S. AULAKH

PRIMARY EXAMINER